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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,674	07/14/2006	Marcel Wijlaars	0470-060131	1707

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,674	WIJLAARS ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. (previously cited) in view of Pissis et al. (previously cited) and Young et al. (Biomaterials 1998 19:1745-1752).

Malmonge et al. teach a copolymer of 2-hydroxyethyl methacrylate (HEMA) and acrylic acid (AA) as artificial articular cartilage in a joint prosthesis (see page 175 column 1 paragraph 2-3; instant claims 8, 9, and 14). They go on to teach that the hydrogels made of this material have negative (ionized) groups fixed within the macromolecular network that are believed to participate in compressive strength of the material (see page 174 column 2 paragraph 1 line15-page 175 column 1 line 5 and page 175 column 1 paragraphs 2-3; instant claim 8). Ionized groups were therefore added to the hydrogel prior to polymerization and were present after polymerization (see page 176 column 1 paragraph 1; instant claim 8). Malmonge et al. also teach the ratio of HEMA to AA in the polymer to be 97.5 to 2.5 as well as 95 to 5 (see page 175 column 1 paragraph 4; instant claim 8). Malmonge et al. do not teach whether this ratio is based upon mass or moles. In the case where the ratio described the molar balance,

the corresponding mass percentage of AA in the polymer would be 1.8% (mass percentage corresponding to 2.5 mol%) and 3.6% (mass percentage corresponding to 5 mol%), as calculated by the examiner. Further, Malmonge et al. also teach the hydrogel being soaked (saturated) in a liquid solution (see figure 1 and caption; instant claim 12). Malmonge et al. do not teach the incorporation of fibers into the taught hydrogel.

Pissis et al. teach the incorporation of Nylon particles (fibers), a swellable polyurethane, into a hydrogel (see page 561 paragraph 1; instant claims 8 and 13). Pissis et al. also teach that all polymer hydrogels would benefit from having their mechanical properties improved and that the inclusion of the Nylon serves this purpose (see page 561 paragraph 1; instant claims 8 and 13). Further Pissis et al. teach the inclusion of the Nylon particles at 10% (see page 561 paragraph 2 lines 17-18; instant claims 8 and 13).

Young et al. teach a fiber reinforced polyHEMA (see abstract). Specifically Young et al. teach that due to the capability of hydrogels to absorb large amounts of water, their polymer networks and mechanical strength can be compromised in the process (see page 1745 column1 lines 7). Young et al. go on to teach fiber reinforcement, that being the inclusion of fibrous material within the hydrogel, to improve the mechanical properties of these otherwise very versatile materials (see page 1745 column 1 line18-column 2 line 5). Further, Young et al. teach a nylon and elastic spandex fiber mesh as one utilized fiber reinforcement (see page 1746 column 1 lines 10-14 and figure 2). As demonstrated by the microscopic images provided, the fibers in

this mesh were longer than one millimeter (see figure 2 panel c and panel d); instant claim 8)

The hydrogel device taught by Malmonge et al. requires mechanical strength and integrity to function for its intended purpose as a joint prosthesis. Since both Pissis et al. and Young et al. teach fiber mesh reinforcement in hydrogel medical devices and Young et al. specifically teach their ability to mechanically reinforce such structures, it would have been obvious to one of ordinary skill in the art at the time of the invention to embed a fiber mesh in the HEMA—AA hydrogel prosthesis of Malmonge et al. Further, since Pissis et al. provide a known proportion of gel to mesh in such devices and Young et al. provide known varieties and dimensions of mesh used to reinforce a hydrogel based medical devices, one of ordinary skill would have also found it obvious to embed nylon/spandex fibers longer than one millimeter and composing approximately 10% of the hydrogel composite in the hydrogel composition of Malmonge et al. Consequently, the saturation of the Pissis et al. and Young et al. modified gel of Malmonge et al. would also have the swellable nylon/spandex fibers saturated as well (see Malmonge et al. figure 1 and caption; instant claim 12). Therefore claims 8-9 and 12-14 are obvious over Malmonge et al. in view of Pissis et al. and Young et al.

Claims 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. in view of Pissis et al. and Young et al. as applied to claims 8-9 and 12-14 above, and further in view of Kou et al. (previously cited).

The teachings of Malmonge et al. in view of Mitsuo et al. and Young et al. make obvious a HEMA-AA hydrogel with 10% Nylon/spandex fibers (dry weight), such that the AA content was from 1-5% (dry weight). However, this modified reference does not teach the use of methacrylic acid (MA) in the hydrogel. Kou et al. teach a HEMA-MA hydrogel as being known in the art at the time of invention (see page 241 column 1 paragraph 1; instant claims 8 and 10). Further, the MA only differs from the AA in that it has an additional methyl group in the place of a hydrogen atom. Thus in a hydrogel HEMA-MA would have negative groups fixed within its macromolecular network like HEMA-AA. Therefore since it would be obvious for one of ordinary skill in the art to pursue known options within their technical grasp, it would have been obvious to use HEMA-MA instead of HEMA-AA in the Pissis et al. and Young et al. modified hydrogel of Malmonge et al. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to use the monomer ratios taught by Malmonge et al. where MA replaces AA. Therefore claims 8 and 10 are obvious over Malmonge et al. in view of Pissis et al. and Young et al. and Kou et al.

Response to Arguments

Applicants' arguments, filed August 28, 2008, have been fully considered but they are not deemed to be persuasive regarding the rejections under 35 USC 103(a). Regarding the applicability of the Pissis et al reference, the authors teach that hydrogels would be benefited by having fiber reinforcement to improve their mechanical integrity. Such a teaching applies broadly to hydrogels and not just those used for

applications later taught by Pissis et al. Applicant also argues that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., uptake of monomer solution by the fibers followed by polymerization) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615